Dataset Integrity Check for the

GFR (DCCT/EDIC) Data File

**Prepared by Michael Spriggs**

**IMS Inc.**

3901 Calverton Blvd, Suite 200 Calverton MD 20705

**April 13, 2015**

**Table of Contents**

1 Standard Disclaimer.............................................................................................................…...................2

2 Study Background......................................................................................................................................2

3 Archived Datasets......................................................................................................................................2

4 Statistical Methods....................................................................................................................................3

5 Results........................................................................................................................................................3

6 Conclusions................................................................................................................................................3

7 References.................................................................................................................................................3

Attachment A: SAS Code.............................................................................................................................12

**Table A**: Variables used to replicate Table 1. Demographic and Clinical Characteristics of the Participants at Baseline and at Closeout of the Diabetes Control and Complications Trial (DCCT) and at Year 16 of the Epidemiology of Diabetes Interventions and Complications (EDIC) Study, According to DCCT Treatment Group...…………………………………………………………………………………………………………………………………………………4

**Table B**: Comparison of values computed in integrity check to reference article Table 1 values……………..5

**Table C**: Variables used to replicate Table 2. Incidence of an Impaired Glomerular Filtration Rate (GFR) and Secondary Outcomes……………………………………………………………………………………..……………………………..11

**Table D**: Comparison of values computed in integrity check to reference article Table 2 values……………11

**1 Standard Disclaimer**

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

**2 Study Background**

The Epidemiology of Diabetes Interventions and Complications (EDIC) study was initiated as follow-up to examine the long-term effects of the original DCCT interventions on diabetic complications such as cardiovascular events and advanced retinal and renal disease. Over 90 percent of participants from the DDCT study were followed by the EDIC study. Similar to the DCCT study, glycosylated hemoglobin values, fasting lipid levels, serum creatinine values, and other risk factors for cardiovascular disease were measured at different intervals for participants. Cardiovascular complications were assessed with standardized means and classified by an independent committee. The EDIC study has found that intensive diabetes therapy reduced risk of cardiovascular disease in patients with type 1 diabetes and that the differences in outcomes between the intensive and conventional therapy groups persist after long-term study.

**3 Archived Datasets**

The SAS data file that was provided by the Data Coordinating Center (DCC) for this replication is located in the “EDIC\EDIC\_Analysis\_Datasets\SAS\_DATA\” folder in the data package.

**4 Statistical Methods**

Analyses were performed to duplicate results for the data published by The DCCT/EDIC Research Group in The New England Journal of Medicine, 2011 December 22. To verify the integrity of the datasets, two tables from the paper were checked (Tables B, D)

**5 Results**

Table 1 in the publication [1], Table 1. Demographic and Clinical Characteristics of the Participants at Baseline and at Closeout of the Diabetes Control and Complications Trial (DCCT) and at Year 16 of the Epidemiology of Diabetes Interventions and Complications (EDIC) Study, According to DCCT Treatment Group. Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are almost exact with only inconsequential discrepancies.

Table 2 in the publication [1], Table 2. Incidence of an Impaired Glomerular Filtration Rate (GFR) and Secondary Outcomes. Table C lists the variables that were used in the replication and Table D compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are exact.

**6 Conclusions**

The NIDDK repository is confident that the GFR data file to be distributed is a copy of the manuscript data.

**7 References**

[1] The DCCT/EDIC Research Group. Intensive Diabetes Therapy and Glomerular Filtration Rate in Type 1 Diabetes. The New England Journal of Medicine 2011;365(25):2366-2376. doi:10.1056/NEJMoa1111732.

**Table A:** Variables used to replicate Table 1. Demographic and Clinical Characteristics of the Participants at Baseline and at Closeout of the Diabetes Control and Complications Trial (DCCT) and at Year 16 of the Epidemiology of Diabetes Interventions and Complications (EDIC) Study, According to DCCT Treatment Group.

|  |  |
| --- | --- |
| Characteristic | Variable(s) |
| **Demographic characteristics**: Age (yr) | Age0, Age99, ATTAGE |
| **Demographic characteristics**: Female sex (%) | Female |
| **Medical history:** Duration of diabetes (yr) | DURYR0, DURYR99 ATT\_DUR |
| **Medical history:** DCCT primary cohort (%)‡ | PRIMARY |
| **Medical history:** Hypertension (%)§ | HT00, HT99, HT |
| **Medical history:** Hyperlipidemia (%)¶ | HLIP00, HLIP99, HLIP |
| **Medical history:** Current smoking (%) | SMOKE00, SMOKE99, SMOKE |
| **Medical history:** Current alcohol use (%) | DRINK00, DRINK99, DRINK |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | MDI |
| **Medical treatment:** Glucose monitoring ≥4 times/day | GLUC4 |
| **Medical treatment:** Any | ANTIHYP |
| **Medical treatment:** ACE inhibitor or ARB | ACEARB |
| **Physical examination findings:** Body-mass index†† | BMI00, BMI99, BMI |
| **Physical examination findings:** Systolic | SBP00, SBP99, SBP |
| **Physical examination findings:** Diastolic | DBP00, DBP99, DBP |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | MBP00, MBP99, MBP |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | HBAEL, DTMEANHB, EDIC\_HBA |
| **Laboratory values:** Median (mg/24 hr) | AER |
| **Laboratory values:** Interquartile range (mg/24 hr) | AER |
| **Laboratory values:** ≥30 mg/24 hr (%) | AER30 |
| **Laboratory values:** ≥300 mg/24 hr (%) | AER300 |
| **Laboratory values:** Serum creatinine (mg/dl) | eSCR |
| **Laboratory values:** Total cholesterol | CHL00, CHL99, CHOL |
| **Laboratory values:** HDL cholesterol | HDL00, HDL99, HDL |
| **Laboratory values:** LDL cholesterol | LDL00, LDL99, LDL |
| **Laboratory values:** Triglycerides | TRG00, TRG99, TRIG |

**Table B:** Comparison of values computed in integrity check to reference article Table 1 values

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | DCCT at Baseline Intensive  Therapy (Manuscript N = 711 | DCCT at Baseline Intensive  Therapy (DSIC N=711) | DCCT at Baseline Intensive  Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 27.1±7.1 | 27.1±7.1 | 0,0 |
| **Demographic characteristics**: Female sex (%) | 48.5 | 48.5 | 0 |
| **Medical history:** Duration of diabetes (yr) | 6.0±4.2 | 6.0±4.2 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 49.0 | 49.0 | 0,0 |
| **Medical history:** Hypertension (%)§ | 0 | 0 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 22.8 | 22.8 | 0 |
| **Medical history:** Current smoking (%) | 20.5 | 20.5 | 0 |
| **Medical history:** Current alcohol use (%) | 37.8 | 37.8 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 0 | 0 | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 0 | 0 | 0 |
| **Medical treatment:** Any | 0 | 0 | 0 |
| **Medical treatment:** ACE inhibitor or ARB | 0 | 0 | 0 |
| **Physical examination findings:** Body-mass index†† | 23.4±2.7 | 23.4±2.7 | 0,0 |
| **Physical examination findings:** Systolic | 114.5±11.3 | 114.5±11.3 | 0,0 |
| **Physical examination findings:** Diastolic | 73.1±8.2 | 73.1±8.2 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 86.9±8.2 | 86.9±8.2 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 9.1±1.6 | 9.1±1.6 | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 11.5 | 11.5 | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 7.2–17.3 | 7.2–17.3 | 0-0 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 11.7 | 11.7 | 0 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 0 | 0 | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.68±0.14 | 0.68±0.14 | 0,0 |
| **Laboratory values:** Total cholesterol | 177.1±32.8 | 177.1±32.8 | 0,0 |
| **Laboratory values:** HDL cholesterol | 50.8±12.3 | 50.8±12.3 | 0,0 |
| **Laboratory values:** LDL cholesterol | 110.3±28.7 | 110.3±28.7 | 0,0 |
| **Laboratory values:** Triglycerides | 80.8±43.3 | 80.8±43.3 | 0,0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | DCCT at Baseline Conventional  Therapy (Manuscript N = 730 | DCCT at Baseline Conventional  Therapy (DSIC N=730) | DCCT at Baseline Conventional  Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 26.5±7.1 | 26.5±7.1 | 0,0 |
| **Demographic characteristics**: Female sex (%) | 45.9 | 45.9 | 0 |
| **Medical history:** Duration of diabetes (yr) | 5.7±4.1 | 5.7±4.1 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 51.8 | 51.8 | 0 |
| **Medical history:** Hypertension (%)§ | 0.3 | 0.3 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 23.3 | 23.3 | 0 |
| **Medical history:** Current smoking (%) | 21.6 | 21.6 | 0 |
| **Medical history:** Current alcohol use (%) | 39.9 | 39.9 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 0 | 0 | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 0 | 0 | 0 |
| **Medical treatment:** Any | 0 | 0 | 0 |
| **Medical treatment:** ACE inhibitor or ARB | 0 | 0 | 0 |
| **Physical examination findings:** Body-mass index†† | 23.5±2.9 | 23.5±2.9 | 0,0 |
| **Physical examination findings:** Systolic | 114.6±11.4 | 114.6±11.4 | 0,0 |
| **Physical examination findings:** Diastolic | 72.9±8.7 | 72.9±8.7 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 86.8±8.6 | 86.8±8.6 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 9.1±1.6 | 9.1±1.6 | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 11.5 | 11.5 | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 7.2–18.7 | 7.2–18.7 | 0,0 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 10.1 | 10.1 | 0 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 0 | 0 | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.68±0.14 | 0.68±0.14 | 0 |
| **Laboratory values:** Total cholesterol | 175.7±33.6 | 175.7±33.6 | 0,0 |
| **Laboratory values:** HDL cholesterol | 50.3±12.3 | 50.3±12.3 | 0,0 |
| **Laboratory values:** LDL cholesterol | 109.1±29.4 | 109.1±29.4 | 0,0 |
| **Laboratory values:** Triglycerides | 81.8±51.3 | 81.8±51.3 | 0,0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | End of DCCT Intensive  Therapy (Manuscript N = 698 | End of DCCT Intensive  Therapy (DSIC N=698) | End of DCCT Intensive  Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 33.4±7.0 | 33.4±7.0 | 0,0 |
| **Demographic characteristics**: Female sex (%) | 49.0 | 49.0 | 0 |
| **Medical history:** Duration of diabetes (yr) | 12.1±4.9 | 12.1±4.9 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 49.1 | 49.1 | 0 |
| **Medical history:** Hypertension (%)§ | 0.7 | 0.7 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 26.0 | 26.0 | 0 |
| **Medical history:** Current smoking (%) | 23.1 | 23.1 | 0 |
| **Medical history:** Current alcohol use (%) | 36.3 | 36.3 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 97.4 | 97.4 | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 52.8 | 52.8 | 0 |
| **Medical treatment:** Any | — | — | 0 |
| **Medical treatment:** ACE inhibitor or ARB | — | — | 0 |
| **Physical examination findings:** Body-mass index†† | 26.6±4.3 | 26.6±4.3 | 0,0 |
| **Physical examination findings:** Systolic | 116.6±11.5 | 116.6±11.5 | 0,0 |
| **Physical examination findings:** Diastolic | 74.8±8.7 | 74.8±8.7 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 88.8±8.7 | 88.8±8.7 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 7.3±0.9 | 7.3±0.9 | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 8.6 | 8.6 | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 5.8–14.1 | 5.8–14.4 | 0-,-0.3 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 10.2 | 10.2 | 0 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 1.4 | 1.4 | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.73±0.14 | 0.73±0.14 | 0 |
| **Laboratory values:** Total cholesterol | 180.3±30.5 | 180.3±30.5 | 0,0 |
| **Laboratory values:** HDL cholesterol | 51.0±12.9 | 51.0±12.9 | 0,0 |
| **Laboratory values:** LDL cholesterol | 112.5±27.1 | 112.5±27.1 | 0,0 |
| **Laboratory values:** Triglycerides | 84.2±52.6 | 84.2±52.6 | 0,0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | End of DCCT Conventional Therapy (Manuscript N = 717 | End of DCCT Conventional Therapy (DSIC N=717) | End of DCCT Conventional Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 32.8±7.0 | 32.8±7.0 | 0,0 |
| **Demographic characteristics**: Female sex (%) | 45.9 | 45.9 | 0 |
| **Medical history:** Duration of diabetes (yr) | 11.7±4.8 | 11.7±4.8 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 51.7 | 51.7 | 0 |
| **Medical history:** Hypertension (%)§ | 1.8 | 1.8 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 29.7 | 29.7 | 0 |
| **Medical history:** Current smoking (%) | 23.2 | 23.2 | 0 |
| **Medical history:** Current alcohol use (%) | 38.9 | 38.9 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 5.0‖ | 5.0‖ | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 3.8‖ | 3.8‖ | 0 |
| **Medical treatment:** Any | — | — | 0 |
| **Medical treatment:** ACE inhibitor or ARB | — | — | 0 |
| **Physical examination findings:** Body-mass index†† | 25.0±3.1‖ | 25.0±3.1‖ | 0,0 |
| **Physical examination findings:** Systolic | 116.6±11.9 | 116.6±11.9 | 0,0 |
| **Physical examination findings:** Diastolic | 74.4±8.9 | 74.4±8.9 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 88.5±8.8 | 88.5±8.8 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 9.1±1.3‖ | 9.1±1.3‖ | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 10.1‖ | 10.1‖ | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 5.8–20.2 | 5.8–20.2 | 0,0 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 17.7‖ | 17.7‖ | 0 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 3.2† | 3.2† | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.72±0.18 | 0.72±0.18 | 0 |
| **Laboratory values:** Total cholesterol | 184.0±37.3 | 184.0±37.3 | 0,0 |
| **Laboratory values:** HDL cholesterol | 51.8±13.1 | 51.8±13.1 | 0,0 |
| **Laboratory values:** LDL cholesterol | 114.6±31.9 | 114.6±31.9 | 0,0 |
| **Laboratory values:** Triglycerides | 88.1±50.8† | 88.1±50.8† | 0,0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | EDIC at Year 16 Intensive Therapy (Manuscript N = 618 | EDIC at Year 16 Intensive Therapy (DSIC N=618) | EDIC at Year 16 Intensive Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 50.4±6.9 | 50.4±6.9 | 0,0 |
| **Demographic characteristics**: Female sex (%) | 48.4 | 48.4 | 0 |
| **Medical history:** Duration of diabetes (yr) | 28.7±5.0 | 28.7±5.0 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 48.7 | 48.7 | 0 |
| **Medical history:** Hypertension (%)§ | 53.7 | 53.7 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 65.7 | 65.7 | 0 |
| **Medical history:** Current smoking (%) | 13.3 | 13.3 | 0 |
| **Medical history:** Current alcohol use (%) | 42.9 | 42.9 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 97.6 | 97.6 | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 65.4 | 65.4 | 0 |
| **Medical treatment:** Any | 56.2 | 56.2 | 0 |
| **Medical treatment:** ACE inhibitor or ARB | 53.1 | 53.1 | 0 |
| **Physical examination findings:** Body-mass index†† | 29.4±13.0 | 29.0±5.8 | 0.4+-7.2 |
| **Physical examination findings:** Systolic | 122.1±14.6 | 122.1±14.6 | 0,0 |
| **Physical examination findings:** Diastolic | 72.5±9.1 | 72.5±9.1 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 89.0±9.6 | 89.0±9.6 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 7.9±1.1 | 7.9±1.1 | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 11.5 | 11.5 | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 7.2–20.2 | 7.2–20.2 | 0,0 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 19.4 | 19.0 | -0.4 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 3.2 | 3.2 | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.85±0.33 | 0.85±0.33 | 0 |
| **Laboratory values:** Total cholesterol | 175.1±36.1 | 175.1±36.1 | 0,0 |
| **Laboratory values:** HDL cholesterol | 61.0±18.7 | 61.0±18.7 | 0,0 |
| **Laboratory values:** LDL cholesterol | 97.4±30.1 | 97.4±30.1 | 0,0 |
| **Laboratory values:** Triglycerides | 84.1±50.8 | 84.1±50.8 | 0,0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | EDIC at Year 16 Conventional Therapy (Manuscript N = 604 | EDIC at Year 16 Conventional Therapy (DSIC N=604) | EDIC at Year 16 Conventional Therapy (DIFF N=0) |
| **Demographic characteristics**: Age (yr) | 49.4±6.9† | 49.4±6.9† | 0,0 |
| **Demographic characteristics**: Female sex (%) | 46.9 | 46.9 | 0 |
| **Medical history:** Duration of diabetes (yr) | 28.2±4.9 | 28.2±4.9 | 0,0 |
| **Medical history:** DCCT primary cohort (%)‡ | 51.5 | 51.5 | 0 |
| **Medical history:** Hypertension (%)§ | 51.2 | 51.2 | 0 |
| **Medical history:** Hyperlipidemia (%)¶ | 65.2 | 65.2 | 0 |
| **Medical history:** Current smoking (%) | 11.8 | 11.8 | 0 |
| **Medical history:** Current alcohol use (%) | 44.7 | 44.7 | 0 |
| **Medical treatment:** Insulin pump or ≥3 daily insulininjections | 96.2 | 96.2 | 0 |
| **Medical treatment:** Glucose monitoring ≥4 times/day | 70.3 | 70.3 | 0 |
| **Medical treatment:** Any | 59.3 | 59.3 | 0 |
| **Medical treatment:** ACE inhibitor or ARB | 57.0 | 57.0 | 0 |
| **Physical examination findings:** Body-mass index†† | 28.2±4.8 | 28.2±4.8 | 0 |
| **Physical examination findings:** Systolic | 121.2±15.2 | 121.2±15.2 | 0,0 |
| **Physical examination findings:** Diastolic | 72.2±8.8 | 72.2±8.8 | 0,0 |
| **Physical examination findings:** Mean arterial pressure (mm Hg) | 88.5±9.6 | 88.5±9.6 | 0,0 |
| **Laboratory values:** Glycated hemoglobin (%)‡‡ | 8.0±1.0 | 8.0±1.0 | 0,0 |
| **Laboratory values:** Median (mg/24 hr) | 13.0† | 13.0† | 0 |
| **Laboratory values:** Interquartile range (mg/24 hr) | 7.2–28.8 | 7.2–28.8 | 0,0 |
| **Laboratory values:** ≥30 mg/24 hr (%) | 22.6 | 23.1 | -0.5 |
| **Laboratory values:** ≥300 mg/24 hr (%) | 7.3‖ | 7.3‖ | 0 |
| **Laboratory values:** Serum creatinine (mg/dl) | 0.89±0.59 | 0.89±0.59 | 0 |
| **Laboratory values:** Total cholesterol | 172.2±37.4 | 172.2±37.4 | 0,0 |
| **Laboratory values:** HDL cholesterol | 60.6±17.5 | 60.6±17.5 | 0,0 |
| **Laboratory values:** LDL cholesterol | 94.9±30.1 | 94.9±30.2 | 0+--0.1 |
| **Laboratory values:** Triglycerides | 82.1±58.3† | 82.1±58.3† | 0,0 |

**Table C:** Variables used to replicate Table 2. Incidence of an Impaired Glomerular Filtration Rate (GFR) and Secondary Outcomes.

|  |  |
| --- | --- |
| Characteristic | Variable(s) |
| Impaired GFR‡ | ANYSCG60 |
| Onset during DCCT | dtedyear |
| Onset during EDIC | dtedyear |
| Estimated GFR <45 ml/min/1.73 m2 | ANYCG45 |
| Estimated GFR <30 ml/min/1.73 m2§ | ANYCG30 |
| End-stage renal disease§ | ANYESRD |
| Combined outcome of impaired GFR or death¶ | E\_COMP |

**Table D:** Comparison of values computed in integrity check to reference article Table 2 values

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | Intensive Diabetes  Therapy Manuscript | Intensive Diabetes  Therapy DSIC | Intensive Diabetes  Therapy DIFF |
| Impaired GFR‡ | 24 | 24 | 0 |
| Onset during DCCT | 1 | 1 | 0 |
| Onset during EDIC | 23 | 23 | 0 |
| Estimated GFR <45 ml/min/1.73 m2 | 24 | 24 | 0 |
| Estimated GFR <30 ml/min/1.73 m2§ | 13 | 13 | 0 |
| End-stage renal disease§ | 8 | 8 | 0 |
| Combined outcome of impaired GFR or death¶ | 53 | 53 | 0 |

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | Conventional Diabetes  Therapy Manuscript | Conventional Diabetes  Therapy DSIC | Conventional Diabetes  Therapy DIFF |
| Impaired GFR‡ | 46 | 46 | 0 |
| Onset during DCCT | 3 | 3 | 0 |
| Onset during EDIC | 43 | 43 | 0 |
| Estimated GFR <45 ml/min/1.73 m2 | 39 | 39 | 0 |
| Estimated GFR <30 ml/min/1.73 m2§ | 23 | 23 | 0 |
| End-stage renal disease§ | 16 | 16 | 0 |
| Combined outcome of impaired GFR or death¶ | 80 | 80 | 0 |

libname gfr "/prj/niddk/ims\_analysis/DCCT\_EDIC/private\_created\_data/edic\_new\_data/GFR2010";

data gfr2010;

set gfr.gfr2010;

%macro means\_table1 (var1, var2, var3);

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var1;

where dtedyear = 0 and GROUP = "EXPERIMENTAL";

title3 "Variable &var1, dtedyear = 0 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var1;

where dtedyear = 0 and GROUP = "STANDARD";

title3 "Variable &var1, dtedyear = 0 and GROUP = STANDARD";

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var2;

where dtedyear = 99 and GROUP = "EXPERIMENTAL";

title3 "Variable &var2, dtedyear = 99 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var2;

where dtedyear = 99 and GROUP = "STANDARD";

title3 "Variable &var2, dtedyear = 99 and GROUP = STANDARD";

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var3;

where dtedyear = 1600 and GROUP = "EXPERIMENTAL";

title3 "Variable &var3, dtedyear = 1600 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=1;

var &var3;

where dtedyear = 1600 and GROUP = "STANDARD";

title3 "Variable &var3, dtedyear = 1600 and GROUP = STANDARD";

%mend means\_table1;

%macro means\_table2 (var1, var2, var3);

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var1;

where dtedyear = 0 and GROUP = "EXPERIMENTAL";

title3 "Variable &var1, dtedyear = 0 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var1;

where dtedyear = 0 and GROUP = "STANDARD";

title3 "Variable &var1, dtedyear = 0 and GROUP = STANDARD";

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var2;

where dtedyear = 99 and GROUP = "EXPERIMENTAL";

title3 "Variable &var2, dtedyear = 99 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var2;

where dtedyear = 99 and GROUP = "STANDARD";

title3 "Variable &var2, dtedyear = 99 and GROUP = STANDARD";

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var3;

where dtedyear = 1600 and GROUP = "EXPERIMENTAL";

title3 "Variable &var3, dtedyear = 1600 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N MEAN STD maxdec=2;

var &var3;

where dtedyear = 1600 and GROUP = "STANDARD";

title3 "Variable &var3, dtedyear = 1600 and GROUP = STANDARD";

%mend means\_table2;

%macro median\_table1 (var1, var2, var3);

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var1;

where dtedyear = 0 and GROUP = "EXPERIMENTAL";

title3 "Variable &var1, dtedyear = 0 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var1;

where dtedyear = 0 and GROUP = "STANDARD";

title3 "Variable &var1, dtedyear = 0 and GROUP = STANDARD";

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var2;

where dtedyear = 99 and GROUP = "EXPERIMENTAL";

title3 "Variable &var2, dtedyear = 99 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var2;

where dtedyear = 99 and GROUP = "STANDARD";

title3 "Variable &var2, dtedyear = 99 and GROUP = STANDARD";

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var3;

where dtedyear = 1600 and GROUP = "EXPERIMENTAL";

title3 "Variable &var3, dtedyear = 1600 and GROUP = EXPERIMENTAL";

proc means data = gfr2010 N median P25 P75 maxdec=1;

var &var3;

where dtedyear = 1600 and GROUP = "STANDARD";

title3 "Variable &var3, dtedyear = 1600 and GROUP = STANDARD";

%mend median\_table1;

%macro freq\_table1 (var1, var2, var3);

proc freq data = gfr2010;

table &var1\*GROUP\*dtedyear / list;

where dtedyear = 0 and GROUP = "EXPERIMENTAL";

title3 "Variable &var1, dtedyear = 0 and GROUP = EXPERIMENTAL";

run;

proc freq data = gfr2010;

table &var1\*GROUP\*dtedyear / list;

where dtedyear = 0 and GROUP = "STANDARD";

title3 "Variable &var1, dtedyear = 0 and GROUP = STANDARD";

run;

proc freq data = gfr2010;

table &var2\*GROUP\*dtedyear / list;

where dtedyear = 99 and GROUP = "EXPERIMENTAL";

title3 "Variable &var2, dtedyear = 99 and GROUP = EXPERIMENTAL";

run;

proc freq data = gfr2010;

table &var2\*GROUP\*dtedyear / list;

where dtedyear = 99 and GROUP = "STANDARD";

title3 "Variable &var2, dtedyear = 99 and GROUP = STANDARD";

run;

proc freq data = gfr2010;

table &var3\*GROUP\*dtedyear / list;

where dtedyear = 1600 and GROUP = "EXPERIMENTAL";

title3 "Variable &var3, dtedyear = 1600 and GROUP = EXPERIMENTAL";

run;

proc freq data = gfr2010;

table &var3\*GROUP\*dtedyear / list;

where dtedyear = 1600 and GROUP = "STANDARD";

title3 "Variable &var3, dtedyear = 1600 and GROUP = STANDARD";

run;

%mend freq\_table1;

run;

%macro inc\_rates (var1, var2);

proc sort data = gfr2010\_nodup;

by group;

proc summary data=gfr2010\_nodup nway;

var &var1 &var2;

class group;

output out=rates(drop=\_type\_ \_freq\_) sum=&var1 &var2;

run;

data rates;

set rates;

\_rate=1000\*(&var1/&var2);

run;

proc print data = rates;

title 'Table of cases, person-years, and rates per 1000 person-years';

var &var1 &var2 \_rate ;

run;

%mend inc\_rates;

%means\_table1(AGE0, AGE99, ATTAGE); run;

%freq\_table1(female, female, female); run;

%means\_table1(DURYR0, DURYR99, ATT\_DUR); run;

%freq\_table1(PRIMARY, PRIMARY, PRIMARY); run;

%freq\_table1(HT00, HT99, HT); run;

%freq\_table1(HLIP00, HLIP99, HLIP); run;

%freq\_table1(SMOKE00, SMOKE99, SMOKE); run;

%freq\_table1(DRINK00, DRINK99, DRINK); run;

%freq\_table1(MDI, MDI, MDI); run;

%freq\_table1(GLUC4, GLUC4, GLUC4); run;

%freq\_table1(ANTIHYP, ANTIHYP, ANTIHYP); run;

%freq\_table1(ACEARB, ACEARB, ACEARB); run;

%means\_table1(BMI00, BMI99, BMI); run;

%means\_table1(SBP00, SBP99, SBP); run;

%means\_table1(DBP00, DBP99, DBP); run;

%means\_table1(MBP00, MBP99, MBP); run;

%means\_table1(HBAEL, DTMEANHB, EDIC\_HBA); run;

%median\_table1(AER, AER, AER); run;

%freq\_table1(AER30, AER30, AER30); run;

%freq\_table1(AER300, AER300, AER300); run;

%means\_table2(eSCR, eSCR, eSCR); run;

%means\_table1(CHL00, CHL99, CHOL); run;

%means\_table1(HDL00, HDL99, HDL); run;

%means\_table1(LDL00, LDL99, LDL); run;

%means\_table1(TRG00, TRG99, TRIG); run;

proc sort data = gfr2010;

by PATIENT;

data gfr2010\_nodup;

set gfr2010;

by PATIENT;

retain have\_esrd have\_impaired\_gfr have\_gfr\_less\_45 have\_gfr\_less\_30 have\_combine\_outcome 0;

if first.PATIENT then do;

have\_esrd = 0;

have\_impaired\_gfr = 0;

have\_gfr\_less\_45 = 0;

have\_gfr\_less\_30 = 0;

have\_combine\_outcome = 0;

end;

if ANYESRD = 1 then have\_esrd = 1;

if ANYSCG60 = 1 then have\_impaired\_gfr = 1;

if ANYCG45 = 1 then have\_gfr\_less\_45 = 1;

if ANYCG30 = 1 then have\_gfr\_less\_30 = 1;

if E\_COMP = 1 then have\_combine\_outcome = 1;

if last.PATIENT then output gfr2010\_nodup;

proc freq data = gfr2010\_nodup;

table

have\_impaired\_gfr\*group

have\_gfr\_less\_45\*group

have\_gfr\_less\_30\*group

have\_esrd\*group

have\_combine\_outcome\*group

/ list missing;

data gfr\_2010\_detailed;

merge gfr2010\_nodup(keep=PATIENT have\_impaired\_gfr) gfr2010;

by PATIENT;

data gfr\_2010\_short(drop=check\_flag);

set gfr\_2010\_detailed;

by PATIENT;

retain check\_flag;

length dtedyear\_flag $4.;

if 0<=dtedyear<=99 then dtedyear\_flag="DCCT";

else if 100<=dtedyear<=9999 then dtedyear\_flag="EDIC";

else do; abort; return; end;

if first.patient then check\_flag=0;

if ANYSCG60=1 and check\_flag=0 then do;

check\_flag=1;

output;

end;

proc freq data = gfr\_2010\_short;

tables have\_impaired\_gfr\*group\*dtedyear\_flag/missing list;

where have\_impaired\_gfr = 1;

title3 'Onset determination';